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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,782

08/08/2006

Sang Yup Lee

4240-148

8819

23448

7590

03/04/2009

INTELLECTUAL PROPERTY / TECHNOLOGY LAW

PO BOX 14329

RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

VOGEL, NANCY TREPTOW

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

03/04/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,782	<b>Applicant(s)</b> LEE ET AL.	
	<b>Examiner</b> NANCY VOGEL	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/8/06</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

Claims 1-13 are pending in the case.

Receipt of the Information Disclosure Statement on 8/8/06 is acknowledged.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7, 11, 12, are rejected under 35 U.S.C. 103(a) as being unpatentable over Francisco et al. (Proc. Natl. Acad. Sci USA 90 10444-10448, 1993), or Charbit et al. (Gene 70, 1, 181-189, 1988) in view of Lee et al. (Trends in Biotechnol., 21, 1, 45-52) and Cristalli et al. (Arch. Biochem. Biophys., 377, 2, 324-333, 2000) (all but Lee et al. cited by applicants).

Francisco et al. and Charbit et al. each disclose a vector for expressing a target protein on the surface of cells, comprising a gene encoding a surface display outer membrane protein, and antibiotic-resistant gene, a promoter, and a gene encoding a target protein in which the target protein is expressed on the surface of the cell in a form fused with the surface display outer membrane protein. (See page 10444, right col., third paragraph, and page 1045-1046, Francisco et al; see abstract, pages 181-185 of

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Charbit et al. ). The different between the references and the instant claims is that the surface display outer membrane is the fadL protein. However, Cristalli et al. disclose the outer member protein FadL and its structure, including externally exposed domains (see abstract, see page 330). Lee et al. disclose the general method of displaying proteins of choice on the surface of microbes using fusions such as C-terminal, N-terminal, or sandwich type fusions of the protein of choice with "carrier proteins", which are outer membrane proteins (see abstract, see page 45-49). It would have been obvious to one of ordinary skill in the art to have utilized the known outer membrane protein FadL in the method disclosed by Francisco et al. and Charbit et al., and further generally disclosed in Lee et al., since the structure of the FadL protein, including proposed regions which are displayed on the surface were known, and since the references all are concerned with surface display type proteins. One would have been motivated to do so by the teachings of Lee et al. , which disclose generally that a protein that is located on the outer membrane surface of a microbe may be used as an anchor protein for surface display, and by Cristalli et al. which particularly disclose the outer membrane protein FadL and its surface topology, making it a good candidate for surface display. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claims 1-7, 11, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francisco et al. (Proc. Natl. Acad. Sci USA 90 10444-10448, 1993), or Charbit et

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al. (Gene 70, 1, 181-189, 1988) in view of Lee et al. (Trends in Biotechnol., 21, 1, 45-52) and Cristalli et al. (Arch. Biochem. Biophys., 377, 2, 324-333, 2000) (cited by applicants) as applied to claim 1-5, 7, 11 and 12 above, and further in view of Park et al. (FEMS Microbiol. Lett. 214, 217, 2002) or DeBoer et al. (Proc. Nat. Acad. Sci USA 80, 21-25, 1983).

Francisco, Charbit, Lee and Cristalli are cited essentially for the reasons set forth above. The difference between the references and the instant claims is that particular promoters, i.e. Tac or gntT104 promoters, are used. However, each of these promoters are known in the art as disclosed by Park et al. and DeBoer et al. (see abstract of both). In addition, Charbit discloses the pTac promoter for the expression of the heterologous protein (see page 182). It would have been obvious to have utilized these known promoters for their known useful properties of controlling high levels of production of a protein of interest, in which the gene encoding said protein of interest is operatively linked to the promoter. One would have been motivated to do so by the ability of each of these promoters to control expression in either a constitutive or inducible manner. The substitution of one promoter for another, for the intended purpose of using the promoter for known properties, would have been obvious to one of ordinary skill in the art. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

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Claims 1-5, 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francisco et al. (Proc. Natl. Acad. Sci USA 90 10444-10448, 1993), or Charbit et al. (Gene 70, 1, 181-189, 1988) in view of Lee et al. (Trends in Biotechnol., 21, 1, 45-52) and Cristalli et al. (Arch. Biochem. Biophys., 377, 2, 324-333, 2000) (cited by applicants) as applied to claim 1-5, 7, 11 and 12 above, and further in view of Georgiou et al. (US Patent 5,508, 192).

Francisco et al., Charbit, Lee, Cristalli are cited essentially for the reasons set forth above. The difference between the references and the instant claims is that protease deficient host microorganisms, particularly E. coli, are used to facilitate the cell surface expression of the target protein. However, Georgiou et al. teaches transformed E. coli having mutations in proteases such as degP, ompT, ptr, or prc, and further teaches the motivation to utilize such strains in order to prevent the degradation of recombinant proteins produced in the cell (see col. 1-4). It would have been obvious to have used such strains in order to prevent degradation of the recombinantly produced protein of interest, as is taught in the reference. One would have been motivated to do so by the desire to produce non-degraded recombinant proteins on the surface of the cell. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claims 1-5, 7, 11, 12, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francisco et al. (Proc. Natl. Acad. Sci USA 90 10444-10448, 1993), or Charbit et al. (Gene 70, 1, 181-189, 1988) in view of Lee et al. (Trends in

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Biotechnol., 21, 1, 45-52) and Cristalli et al. (Arch. Biochem. Biophys., 377, 2, 324-333, 2000) (cited by applicants) as applied to claims 1-5, 7, 11, 12 above, and further in view of Pan et al. (US Patent 6,071,725).

Francisco, Charbit, Lee, and Cristalli are cited essentially for the reasons set forth above. The difference between the references and the instant claims is that the foreign gene that is expressed is a lipase gene. However, Pan et al. disclose a method of recombinant production of a lipase on the cell surface using a surface display protein in a recombinant microorganism (see col. 4-5). It would have been obvious to have expressed lipase in the method disclosed by the Francisco Charbit, Lee and Cristalli references, since such a method was known to be useful for the surface of a protein of choice, and since Pan et al. disclosed that lipase may be expressed using a method of surface display of a target protein by fusion with a surface protein in a microorganism. One would have been motivated to do so by the desire to express a lipase protein on the surface of a microorganism, as taught by the reference. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

### ***Conclusion***

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/  
Primary Examiner, Art Unit 1636

NV  
2/23/09